

REMARKS

Claims 11, 13 and 15 are pending and are rejected.

Claim Objection

Applicant has amended the claims as requested to correct the typographical error and overcome the objection.

Claim Rejections Under 35 U.S.C. §112

Claims 11, 13 and 15 are rejected under 35 U.S.C. §112 ¶2 as indefinite.

The Examiner states that "pulmonary inflammatory process," "chronic repair process," and "clinical status" are relative terms that render the claims indefinite. Applicant has amended the claims to delete these phrases and overcome this rejection.

The Examiner states that claims 11-13 and 15 are indefinite because claim 11 "does not match or clearly relate back to the preamble." Although Applicant disagrees and asserts his preamble is adequate for his method, Applicant has amended the claims to overcome this rejection.

For at least these reasons, Applicant asserts claim 11-13 and 15 are sufficiently definite.

Claims 11, 13 and 15 are rejected under 35 U.S.C. §112 ¶1 as not enabled. Applicant has amended claim 11 to limit the pulmonary tissues to lung fluid, lung biopsy, and bronchoalveolar fluid in which RELM β levels are analyzed as an indicator of asthma.

Applicant disagrees with the Examiner's assertion that the "specification provides little or no guidance as to how to measure RELM α or RELM β qualitatively or functionally, as required by claim 15." The specification qualitatively and functionally describes the effect of RELM β on lung function (p.16 lines 6-21), lung histology (p.20 line 12 to p.22 line 21), and fibroblast motility (p.22 line 22 to p.23 line 21). This disclosure provides examples of how RELM β levels can be determined by examining the physical effects of RELM β on animal lung tissue or by evaluating its effect in an *in vitro* assay of fibroblast motility.

Applicant disagrees with the Examiner's assertion that undue experimentation would be required to determine RELM β protein expression levels in the lung tissues of a patient. Protein expression is a readily determinable parameter, not requiring undue experimentation by one of ordinary skill in the art. Applicant has disclosed that RELM β mRNA levels are increased in the rodent model of asthmatic inflammation (p. 17 lines 16-31) and that intratracheal application of RELM β protein induces the hallmarks of pulmonary inflammation associated with asthma (p.20 line 12 to p. 22 line 21). Further, Applicant discloses that one skilled in the art can easily determine RELM β protein levels in lung tissue by Western blot analysis and staining of tissue sections with the proper probe (p. 28 lines 2-7). Artis (Proc. Natl. Acad. Sci. USA September 101 (2004) 13597, Fig. 4), prior art made of record by the Examiner, discloses that changes in RELM β protein expression can be readily detected by Western blot and immunofluorescent stains of mouse tissue sections. Thus, undue experimentation is not required for one having ordinary skill in the art to determine increased RELM β levels in lung tissue and fluids of patients.

Claims 11, 13 and 15 are rejected under 35 U.S.C. §112 ¶1 as not described because the "specification does not provide adequate written description for the claimed genus of methods of

assessing/indicating pulmonary diseases and pulmonary inflammatory processes.” Applicant has amended the claims to limit pulmonary diseases to asthma to overcome this rejection.

For at least these reasons, Applicant asserts claim 11-13 and 15 are fully enabled and described. Applicant respectfully asserts that the rejections under 35 U.S.C. §112 are overcome and requests their withdrawal.

Claim Rejections Under 35 U.S.C. §102

Claims 11, 13 and 15 are rejected under 35 U.S.C. 102(b) as anticipated by Holcomb.

The Examiner states that Holcomb discloses “FIZZ1 (RELM α) is associated with pulmonary inflammation.” Applicant has amended the claims delete recitation of RELM α to overcome this rejection. As known to one of ordinary skill in the art, RELM β and RELM α are different proteins.

For at least this reason, Applicant asserts that Holcomb does not anticipate claims 11-13 and 15, and respectfully requests the rejection to be withdrawn.

CONCLUSION

Applicant believes the Application is in condition for allowance. The fee for a one-month response extension is being paid herewith (see electronic Fee Calculation sheet).

The Examiner is invited to contact Applicant’s undersigned representative with questions.

Respectfully submitted,

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